

Appl. No. : 09/221,931  
Filed : December 28, 1998

**REMARKS**

Claim 11 has been amended to clarify the invention. New claim 21 has been added. Claims 11 and 17-21 are pending in this application. Support for the amendments is found in the existing claims and the specification. Support for the amendment to claim 11 is found in Figure 2. Support for new claim 21 is found at page 5, lines 7-8, present specification. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

**Information Disclosure**

The Examiner states that the Information Disclosure Statement filed 2/23/00 was submitted without reference copies. Consequently, the Information Disclosure Statement of 2/23/00 is re-submitted herewith. All references are attached thereto. Consideration is respectfully requested.

**Rejection of claims 11 and 17-20 under 35 U.S.C. § 102(a)**

The Examiner maintains the rejection of claims 11 and 17-20 under 35 U.S.C. § 102(a) as clearly anticipated by Naasani et al. Unfortunately, it appears that the certified translation of Applicants' priority document was lost along with the references which should have accompanied the response of 2/23/00. Accordingly the verified translation is resubmitted with this response. In view of the verified English translation of Japanese patent application 361282/1997, filed December 26, 1997, withdrawal of this ground of rejection is respectfully requested.

**Rejection of claims 1-8 under 35 U.S.C. § 102 (b) and anticipated by or, in the alternative, under 103(a).**

The Examiner has rejected claims 1-8 (presumably 11 and 17-20) as being unpatentable over either of Fujiki et al. or Liao et al or admitted prior art. The Examiner asserts that the prior art teaches that green tea is effective as a cancer preventive and that catechins are known to be an active ingredient of tea. Consequently, under principles of inherency, green tea drinking would perform the claimed method.

In response, Applicants have amended claim 11 to recite that the concentration of catechins is at least 10 µM. Support for this amendment is found in Figure 2 .

None of the cited references teaches a catechin concentration of at least 10  $\mu$ M and none of the cited references teaches the use of a catechin for telomerase inhibition. Although the cited references do teach some purification of EGCG from green tea extract, the amount used is given in mg and the degree of purification is not disclosed. So the final concentration applied is unknown. Consequently, none of the cited references anticipate the claimed invention.

Furthermore, none of the cited references render Applicants' invention obvious as presently claimed. In order to provide a *prima facie* case of obviousness, the Patent and Trademark Office has the burden to provide a motivation, teaching, or suggestion to create the claimed invention. *See, e.g., In re Fine*, 5 U.S.P.Q.2d 1597 (Fed. Cir. 1988). Such motivation, teaching or suggestion is absent in any of the references cited by the Examiner, alone or in combination because none of the cited references teaches anything about the effects of catechins on telomerase. In view of the cited references, one of ordinary skill in the art would not expect catechins to have any effect on telomerase. Consequently, the cited references do not render Applicants' invention obvious and this ground of rejection may be properly withdrawn.

**Rejection of claims 11 and 17-20 under 35 U.S.C. § 101**

The Examiner asserts that although inhibition of telomerase activity is credible and supported by experimental evidence, it is not a specific and substantial activity because there is no direct relationship between inhibition of telomerase and growth/activity of cancer cells.

The "Revised Interim Utility Guidelines Training Materials" defines a "substantial utility" as a utility that defines a "real world" use. In the present case, the "real world" use is cancer treatment. Clear evidence exists for the nexus between telomerase inhibition and anticancer effects (see Naasani et al, Abstract). "[H]uman telomerase has been proposed as a novel and potentially highly selective target for cancer therapy" (Naasani et al. page 391, col. 2, paragraph 1). Consequently, the inhibition of telomerase by the claimed method has a real world use in cancer treatment and prevention.

Likewise, the "Guidelines" define a specific utility as a utility that is specific to the subject matter claimed. The claimed utility is specific as it is drawn to effects on a specific chromosomal structure, the telomere. Effects of catechins on telomerase activity and telomere structure can be determined by assays which are disclosed in the present specification (See Example 6 and Figure 7).

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Consequently, the presently claimed invention meets the requirements of 35 U.S.C. § 101 as the claimed invention is drawn to a utility which is credible, specific, and substantial.

### CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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Dated: 10-2-00

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